# Vaccine Identification Standards Initiative (VISI)

## Summary of Conference Call
## March 5, 1999
## 10:00 AM - 12:00 PM EST

**CALL PARTICIPANTS**

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| Dr. Bruce Weniger (moderator) | National Immunization Program/CDC |
| Dr. Robert Chen | National Immunization Program/CDC |
| Bindi Patel | National Immunization Program/CDC |
| Tom Gilbert | American Academy of Family Physicians |
| Belinda Shell | American Academy of Family Physicians |
| Dinny Smith | Pharmacy Division/Texas Department of Health |
| Gene Trautman | Pharmacy Division/Texas Department of Health |
| Jim Allen | Pharmacy Division/Texas Department of Health |
| Del Carvell | Georgia Immunization Program |
| Don Dumont | Oregon Immunization Program |
| John Kropas | Wyeth-Lederle Vaccines & Pediatrics |
| Lugene Maher | Wyeth-Lederle Vaccines & Pediatrics |
| Gina Butler-Galliera | SmithKline Beecham Pharmaceuticals |
| Carol Krueger | Center for Biologics Evaluation and Research/FDA |
| Karen Chaitkin | Center for Biologics Evaluation and Research/FDA |
| Vickie Rementer | AutoImage ID |
| Jim Hahn | AutoImage ID |
| Dave | AutoImage ID |
| John Roberts | Uniform Code Council, Inc. |
| Glen Ford | Uniform Code Council, Inc. |

**SUMMARY**

**VISI Introductions**

Dr. Bruce Weniger welcomed all VISI participants and asked everyone to identify themselves. He reviewed the agenda for the conference call and encouraged VISI participants to ask representatives of both Data Matrix and Reduced Space Symbology (RSS) questions regarding their symbologies.

Before the conference call, VISI participants were sent information on high-information-density, two dimensional barcoding symbologies including Data Matrix and RSS. Representatives from these two symbologies joined the conference call. These symbologies were discussed, as follows.

**Presentation on Data Matrix**

Ms. Vickie Rementer, Mr. Jim Hahn and Mr. Dave Bubnoski represented Auto Image ID Inc., a company that designs, manufactures, and markets two dimensional bar/matrix code scanning equipment. Ms. Rementer's presentation focused on the pharmaceutical application of Data Matrix codes. Major advantages of using this symbology included:

- Size- Data Matrix is made up of "cells" and is easily scaleable from large symbol sizes down to very small symbol sized which typically range from 1/10th to 1/4th of an inch square.

- Printable- Marking of Data Matrix codes can applied to a variety of surfaces. The symbology can be printed by ink jet, laser, chemical etchings and other methods. Direct marking allows the symbol to be imprinted directly on the surface of an item.

- Density- Data Matrix codes provide a high density of information in a given physical area. This symbology contains a minimum of 30 times more information density than a bar code and only takes up less than 1/30th the space.

- Accuracy- Data Matrix codes are imbedded with error detection and correction capabilities to ensure absolute read accuracy.

Ms. Rementer also mentioned that this symbology has been used widely in the pharmaceutical industry. She listed a few examples such as outside packaging of products, cut labels and printed cartons, label revisions, and clinical trials product identification.

A question was raised regarding placement of the Data Matrix code on curved surfaces, such as vaccine vials. Mr. Bubnowski responded by stating that this symbology can be placed on curved surfaces through different types of marking systems. Mr. Hahn reiterated that the size of Data Matrix code is a major advantage in this industry.

Ms. Butler-Galliera asked if this symbology allowed for printing lot numbers and expiration dates on-line. Mr. Hahn explained that printing Data Matrix codes on-line is possible and can be done by various methods. The most common and by far most familiar method is a printed label. These may be individual preprinted or printed on-demand labels, or overall package labels that include a 2D symbol as

part of label design. The methods are the same as a 1D process. In addition, the label generation software is readily available from many vendors for a wide variety of popular printers. Another option is printing directly on an item's surface (called direct marking)which can be a a viable and cost effective marking technique for some high volume applications. Data Matrix symbology printing is supported by all the popular inkjet printer manufacturers. Because the Data Matrix symbol can be very small, precision laser etching is used with high accuracy on an extremely wide variety of surfaces. Laser direct marking can provide permanent identification for security and authentication applications as well as marking in a very small area and tight locations.

Mr. Dumont asked how big the code would have to be to be printed on a inkjet printer. Mr. Bubnoski replied that the typical size of a printed Data Matrix label would be 10 mil cell size, which can hold up to 25 alphanumeric characters. The cells, sometimes referred to as elements, are of equal size and form a two dimensional array which resembles a checker board. Because the elements are all the same size it can be made very small without the limiting 'minimum feature size' considerations inherent in bar code technology. It is easily scaleable by changing the size of the cells.

Mr. Kropas asked how large the quiet zone would be for this symbology. Mr. Bubnoski explained that the quiet zone would equal 1 mil around the symbol. Therefore, a 10 mil cell would have a quiet zone of 10 mil.

Dr. Weniger asked if there were any intellectual property issues or royalties involved with using this symbology. Mr. Hahn responded by stating that Data Matrix is in the Public Domain and also standardized by the International Standards Organization (ISO).

Mr. Carvell inquired about the equipment needed by local and county health departments to read this symbology. Mr. Hahn replied that scanners and verifiers were needed to encode the symbology. The cost for scanners range from $1200 to $2400.

Dr. Weniger asked what would be the recommended smallest mil size that the cheapest scanner would read. Mr. Bubnoski replied that the standard density of the 10 mil symbol would be readable by the handheld scanner. He also advocated for imaging technology, which is the new wave of the future.

Ms. Maher inquired about the use of this technology internationally. Mr. Hahn stated that a large portion of this technology is being used internationally. Mr. Bubnoski also stated that software to read Data Matrix is available in many languages and there is an infrastructure to support an international market.

**Presentation on Reduced Space Symbology (RSS) and Composite Symbology**

Mr. John Roberts and Mr. Glen Ford represented the Uniform Code Council, Inc. (UCC), the organization involved in developing RSS. Mr. Roberts gave VISI participants some background information regarding the evolution of RSS and the status of its development. The UCC, in conjunction with their partners at the EAN International, are voluntary standards organizations that together manage the UCC/EAN system which recently introduced two new symbologies, RSS and the composite. The

RSS family contains four linear symbologies which include, RSS-14 Standard, RSS-14 Limited, RSS Expanded, and RSS-14 Stacked. The UCC-EAN linear codes can be combined with a unique two-dimensional component to form a new class of symbology called the UCC-EAN Composite Symbology. A UCC-EAN Composite symbol consists of a linear symbol, allowing for item identification, and an adjacent two dimensional component, allowing to encode supplementary information such as lot numbers and expiration dates. Some important points mentioned about this symbology included:

- The composite symbol will allow you to put more information in less space.
- The new symbologies are expected to enhance existing barcoding capabilities, not replace current symbols.
- UCC and EAN are working with various industries to develop a global standardization of product identification.
- These symbologies will be placed in the public domain.
- The composite symbology will allow for the co-existence of symbologies already being used and can be supported by both laser and imaging based scanning equipment.

Mr. Trautman asked if this new symbology would be replacing Electronic Data Interchange (EDI). Mr. Ford stated that this was not the case and that the new symbologies were introduced to improve system processing.

Dr. Weniger asked about the costs of scanning equipment. Mr. Roberts explained that he could not answer this question because the UCC is not in the business to endorse products. He did state that there is a wide variety of scanning equipment. Mr. Ford stated that the linear line imaging scanners could encode both RSS and Data Matrix. Mr. Hahn agreed that their imaging scanners could read both symbologies.

Mr. Roberts suggested that VISI be concerned with standardizing the information needed to be put on the labels so that health departments across the U.S. can obtain the same information. Dr. Weniger agreed and stated that VISI has agreed upon the minimum requirements which include 1) NDC number, 2) Lot number and 3) Expiration date to be included on each label.

Mr. Roberts also stated that the UCC is setting up pilot programs to support the goal of creating guidelines and standards in specific application areas. The Pilot Teams will work in a particular application area to provide a "proof-of-concept" and once proven, to provide cost/benefit analysis within that same application area. Dr. Weniger advised vaccine manufacturers if they were interested to contact Mr. Roberts.

Dr. Weniger stated that VISI coordinators will draft standards for public comment and publish a set of voluntary standards. It will be up to the individual vaccine manufacturers to work with the FDA to implement the standards.

Dr. Weniger thanked the representatives from Auto Image ID and UCC for participating in the VISI conference call. He asked VISI participants if there were any other comments. None responded and the call was ended.

**Contact**

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